



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,965	03/29/2001	Thomas Innerarity	220002059710	8308
25226	7590	06/02/2004	EXAMINER	
MORRISON & FOERSTER LLP			GUPTA, ANISH	
755 PAGE MILL RD			ART UNIT	
PALO ALTO, CA 94304-1018			PAPER NUMBER	

1654

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/822,965

Applicant(s)

INNERARITY ET AL.

Examiner

Anish Gupta

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 19 and 20 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. The amendment filed 3-8-04 is acknowledged. Claims 1-13, 15-17 and 21-28 were canceled. Claim 18 was amended. Claims 14, 18-20 are pending in this application.
2. All rejection made in the previous office action and not cited herein are hereby withdrawn.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 14 and 20 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicants argue that the mutation in Site B results in a proteoglycan-receptor+phenotype. Thus, the claimed apo-B100 protein contains not only sequence alteration but also an associated change in activity.

Applicants' arguments have been considered but have not been found persuasive.

The claims are drawn to a Apo-B100 protein comprising a proteoglycan receptor mutation in Site B. The specification defines a proteoglycan receptor mutant apo-B100 as apo-B100 sequence having any amino acid substitution in positions 3358-3367, and especially 3363, 3362, 3364 and 3359 (see page 17-18 of the specification). As stated in the previous office action, Law et al. teach Hamster apo sequence that has the sequence SRLTRKRGLK in position 3359-3367 (see page 1114 of Law et al.). This sequence meets the claimed limitation of claims 14 since the 3359 Serine residue is different than the 3359 Threonine residue of human apo-B100. Thus, the structure of a protein

Art Unit: 1654

containing “proteoglycan receptor+mutation in Site B,” is inclusive of the Rat apo sequence.

Although the reference maybe silent with respect to activity, one could conclude that since the structure is the same, the activity would be the same. Since the protein is found to occur naturally, is non-statutory subject matter.

To overcome this rejection, Applicants should place the limitation of “isolated” within the claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 14 and 19 remain rejected under 35 U.S.C. 102(b) as being anticipated by Law et al. (J. Lipid Research).
5. Claims 14 and 20 remain rejected under 35 U.S.C. 102(b) as being anticipated by Leroy et al. (J. Lipid Research) and Law et al. (J. of Lipid Research).

Applicants argue, for both rejections, that the references do not teach a protein that has “reduced binding activity to proteoglycan but with normal binding activity to the LDL receptor.” Since the reference does not teach this activity, the claims cannot be anticipated.

Applicant’s arguments have been considered but have not been found persuasive.

The specification defines site B as region 3359-3369 (see page 15). Mutations are defined as the substitution of any amino acid (see page 18). Thus a site B substitution is any amino acid

Art Unit: 1654

substitutions differing from native apo-B100 in region 3359-3369. Specifically, the specification states that mutant of apo-B100 as an amino acid sequence different from the native apo-B100 in positions 3363, 3362, 3364, and 3359 (see page 17). Note that the reference of Law et al. teach rabbit apo-b contains two different amino acids in positions 3358 and 3359 and Pig sequence disclosed is SLMRKRGGL in positions 3359-3367 (see page 1114). Note that 3359 and 3361 differ from the native human apo-B100 and therefore would qualify as mutations in these positions with respect to human apo-B100. Although the reference does not talk about activity, it must not be forgotten that the MPEP states:

“Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, supra.

Here the proteins have similar structures and thus would necessarily possess the characteristics of the claimed product.

Rejections are maintained.

6. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

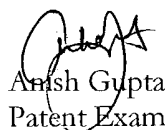
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


Art Unit: 1654

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

 5/26/04  
Anish Gupta  
Patent Examiner

  
**BRENDA BRUMBACK**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**